

CLAIMS

What I Claim Is:

1. A diagnostic sanitary test strip device for measuring an analyte of interest in a heterogenous fluid sample, said test strip comprising:

(a) an upper support layer defining a sample receiving port for receiving the fluid sample therein;

(b) means for retaining the fluid sample to prevent spillage of the sample from said strip to make said test strip sanitary;

(c) means, in vertical alignment and contiguous contact with said sample receiving port, for uniformly spreading the fluid sample in said receiving port before allowing said fluid sample to vertically pass through said spreading means;

(d) means, in contiguous contact with said spreading means, for filtering the fluid sample received from said spreading means to remove at least one undesirable element in the fluid sample prior to passing the fluid sample through said filtering means;

(e) a reaction membrane, in contiguous contact with said filtering means, having a predetermined porosity, said membrane retaining a reagent solution capable of reacting with the analyte of interest to produce a color change in said membrane corresponding to the amount of analyte present in the fluid sample; and

(f) a lower support layer in contiguous contact with said membrane and having a reaction viewing port in vertical alignment with said membrane for displaying said color change, said lower support being operatively associated with said upper support to secure said test strip.

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~~2. The test strip as recited in claim 1, wherein said retaining means comprises a plurality of dam partitions penetrating said test strip, said dam partitions being defined by indentations formed in said upper layer.~~

~~3. The test strip of claim 2, wherein said dam partitions are oriented around said receiving port.~~

<sup>3</sup>  
4. The test strip of claim 1, wherein said reagent solution comprises reactants which facilitate an end-point test in a corresponding reflectance meter.

<sup>4</sup> <sup>3</sup>  
5. The test strip of claim ~~4~~, wherein said reagent solution includes an enzyme solution.

<sup>5</sup> <sup>3</sup>  
6. The test strip of claim ~~4~~, wherein said reagent solution in said filtering means comprises a red blood cell binding agent for capturing red blood cells from the fluid sample.

<sup>6</sup> <sup>3</sup>  
7. The test strip of claim ~~4~~, wherein said red blood cell binding agent comprises lectins.

<sup>7</sup>  
8. The test strip of claim 1, wherein said reagent solution in said filtering means is capable of detecting glucose analytes in the fluid sample.

<sup>8</sup> <sup>7</sup>  
9. The test strip of claim ~~8~~, wherein said reagent solution in said filtering means includes an indicator chemical capable of visually indicating the amount of glucose analytes in the fluid sample.

<sup>9</sup>  
10. The test strip of claim 1, wherein said filtering means comprises a separating layer having a plurality mesh openings and

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being treated with a chemical solution capable of capturing said undesirable element for filtering the fluid sample prior to passing the fluid sample through said mesh openings.

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~~11~~. The test strip of claim ~~6~~, wherein the mesh openings in said separating layer are smaller than said mesh openings in said spreading screen.

<sup>11</sup>

~~12~~. The test strip of claim 1, wherein said membrane comprises an isotropic membrane such that said membrane has a substantially uniform porosity.

<sup>12</sup>

<sup>11</sup>

~~13~~. The test strip device of claim ~~12~~, wherein said membrane comprises a material containing polysulfone.

<sup>13</sup>

5 ~~14~~. The test strip device of claim 1, wherein said upper layer comprises a plurality of detents for mating with securing posts in a corresponding reflectance meter.

<sup>14</sup>

~~15~~. The test strip of claim 1, wherein said reagent solution in said filtering means is capable of detecting cholesterol analytes in the fluid sample.

<sup>15</sup>

10 ~~16~~. The test strip of claim 1, wherein said reagent solution in said filtering means is capable of detecting osteoporosis analytes in the fluid sample.

<sup>16</sup>

~~17~~. The test strip of claim 1, wherein said reagent solution in said filtering means is capable of detecting ketones analytes in the fluid sample.

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~~18~~. The test strip of claim 1, wherein said reagent solution in said filtering means is capable of detecting theophylline analytes in the fluid sample.

~~19~~. The test strip of claim 1, wherein said reagent solution in said filtering means is capable of detecting H1AC analytes in the fluid sample.

~~20~~. The test strip of claim 1, further comprising means for properly orienting said test strip in a corresponding meter.

~~21.~~ The test strip of claim ~~20~~, wherein said orienting means comprises a light absorption medium on an exposed surface of said upper support layer.

22. A diagnostic sanitary test strip device for measuring an analyte of interest in a heterogenous fluid sample, said test strip comprising:

(a) an upper support layer defining a sample receiving port for receiving the fluid sample therein;

(b) means for retaining the fluid sample to prevent spillage of the sample from said strip to make said test strip sanitary;

(c) a spreading screen, in vertical alignment and contiguous contact with said sample receiving port, for receiving the fluid sample, said spreading screen having mesh openings of a predetermined size sufficient for facilitating the uniform distribution of the fluid sample over said screen in the area of said receiving port before allowing said fluid sample to vertically pass through said mesh openings;

(d) a separating layer, in contiguous contact with said spreading screen, for receiving the fluid sample from said spreading screen, said separating layer having mesh openings and

(e) a reaction membrane, in contiguous contact with said filtering means, having a predetermined porosity, said membrane retaining a reagent solution capable of reacting with the analyte of interest to produce a color change in said membrane corresponding to the amount of analyte present in the fluid sample; and

23. The tests trip as recited in claim 22, wherein said retaining means comprises a plurality of dam partitions penetrating said test strip, said dam partitions being defined by indentations formed in said upper layer.

25. The test strip of claim 22, wherein said reagent solution comprises reactants which facilitate an end-point test in a corresponding reflectance meter.

26. The test strip of claim 25, wherein said reagent solution includes an enzyme solution.

27. The test strip of claim 22, wherein said reagent solution in said filtering means comprises a red blood cell binding agent for capturing red blood cells from the fluid sample.

28. The test strip of claim 27, wherein said red blood cell binding agent comprises lectins.

29. The test strip of claim 23, wherein said reagent solution in said filtering means is capable of detecting glucose analytes in the fluid sample.

30. The test strip of claim 29, wherein said reagent solution in said filtering means includes an indicator chemical capable of visually indicating the amount of glucose analytes in the fluid sample.

31. The test strip of claim 23, wherein the mesh openings in said separating layer are smaller than said mesh openings in said spreading screen.

32. The test strip of claim 23, wherein said membrane comprises an isotropic membrane such that said membrane has a substantially uniform porosity.

33. The test strip device of claim 32, wherein said membrane comprises a material containing polysulfone.

34. The test strip device of claim 23, wherein said upper layer comprises a plurality of detents for mating with securing posts in a corresponding reflectance meter.

35. The test strip of claim 23, wherein said reagent solution in said filtering means is capable of detecting cholesterol analytes in the fluid sample.

5 36. The test strip of claim 23, wherein said reagent solution in said filtering means is capable of detecting osteoporosis analytes in the fluid sample.

37. The test strip of claim 23, wherein said reagent solution in said filtering means is capable of detecting ketones analytes in the fluid sample.

10 38. The test strip of claim 23, wherein said reagent solution in said filtering means is capable of detecting theophylline analytes in the fluid sample.

15 39. The test strip of claim 23, wherein said reagent solution in said filtering means is capable of detecting H1AC analytes in the fluid sample.

40. The test strip of claim 23, further comprising means for properly orienting said test strip in a corresponding meter.

20 41. The test strip of claim 40, wherein said orienting means comprises a light absorption medium on an exposed surface of said upper support layer.

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